REMARKS

Claims 1, 3-5, 8-10, 14-22, and 36 are allowed.

Claim 23 is rejected as being indefinite because "ionically conductive medium" is not positively recited. Claim 23 has been amended to delete the recitation.

In addition, claims 23-25 and 30 are rejected as being anticipated by US Patent No. 5,906,613 to Mulier.

Claim 23 has been amended to recite limitations of:

> differential current density electrode means at the distal end of the elongated body for (1) defining a first electrode surface and a second electrode surface, (2) delivering pacing stimulation to myocardial tissue via intimate contact with the second electrode surface, and (3) producing a first current density at the first electrode surface and a second current density at the second electrode surface, when a current is delivered via the conductor, wherein the first current density is smaller than the second current density so that the second electrode surface forms a high impedance and low polarization stimulating electrode; and
>
> fixation means for affixing the second electrode surface in contact with myocardial tissue.

The corresponding structures that are linked in the specification to the specified functions of the means-plus-function limitations include the structures of Figs. 1A and 1B. [1]

[1] Figs. 2A, 2B, and 3A-C are also embodiments that have corresponding structure that is linked to the specified functions of the differential current density electrode means at the distal end of the elongated body.

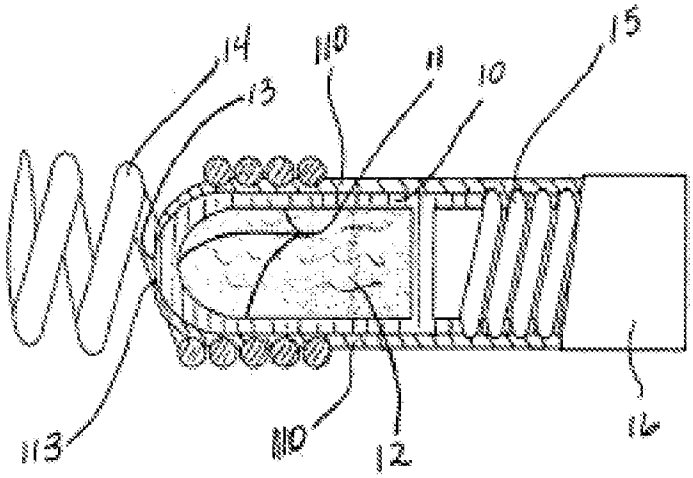

FIGURE 1A

[0012] **FIG. 1A** further illustrates conductive structure **10** including a first electrode surface **11**, a second electrode surface **13** and insulative housing **110** including a cavity **12** and a port **113**, and an insulated helical fixation member **14** coupled to insulative housing **110** and extending distally in order to affect fixation of second electrode surface **13** against a segment of tissue via rotation of fixation member **14** as is well known to those skilled in the art. Fixation member **14** may be formed of a non-conductive biocompatible material, for example a rigid polymer such as PEEK, or a ceramic, or of a conductive material including a biocompatible insulative coating, for example stainless steel having a parylene coating or tantalum having an oxide coating.

[**0013**] According to embodiments of the present invention cavity **12** enclosed by first electrode surface **11** is filled with an ionically conductive medium in intimate contact with first electrode surface **11**; first surface **11** has a surface area approximately greater than or equal to approximately 10 square millimeters, and port **113** circumscribes second electrode surface **13**, which has a surface area between approximately 0.1 square millimeters and 4 square millimeters, to form a high impedance and low polarization DCD electrode wherein a relatively high current density is formed at second electrode surface **13** and a relatively low current density is formed at first electrode surfacel **1** when a current is delivered from connector pin **17** to conductive structure **10** via conductor **15**. The ionically conductive medium may be

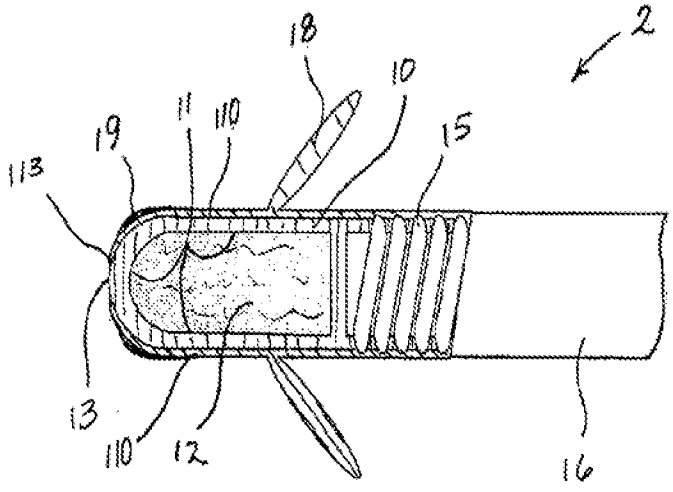

FIGURE 1B

[0015] **FIG. 1B** is a plan view including a partial section of a distal portion of a medical electrical lead including a DCD electrode according to another embodiment of the present invention. **FIG. 1B** illustrates lead **2** including many elements in common with lead **1** illustrated in **FIG. 1A** but a set of resilient tine members **18** replaces insulated helical fixation element **14** to assist in holding second electrode surface **13** circumscribed by port **113** in contact with tissue according to means known to those skilled in the art. **FIG. 1B** further illustrates lead **2** including a steroid-loaded monolithic controlled release device (MCRD) **19** formed about insulative housing **110** in proximity to port **113**. Steroid-loaded MCRD **19** reduces inflammation of contacting tissue and, according to one embodiment, is a biocompatible polymer matrix impregnated with dexamethasone phosphate, either adhered to an integral part of insulative housing **110**; additional materials comprising steroid-loaded MCRD's and methods for forming them are well known to those skilled in the art.

Mulier discloses an ablation catheter for mapping and ablating tissue with RF energy. Mulier is not directed to stimulating electrode for myocardial tissue. The catheter is illustrated in Fig. 7 and a cutaway view of its distal end is shown in Fig. 10.

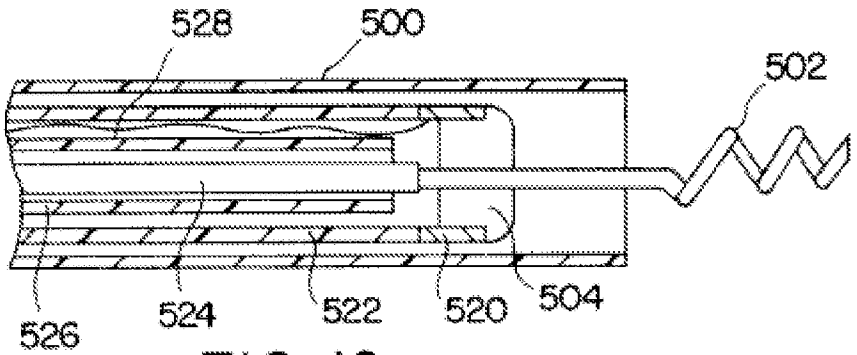

FIG. 10

The distal end has a hollow, needle-like, helical electrode 502 supplied with a conductive fluid through tube 524. A tube 522 surrounds tube 524 and defines a fluid

flow path for "return flow" for fluid that passes through the annulus between tube 526 and tube 524. A plastic plug 504 seals the end of tube 522. A ring electrode 520 is fitted to plug 504. Electrode 520 is coupled to tissue by conductive fluid discharged through the annulus between tube 500 and tube 522.

Just as allowed claim 1 is not anticipated by Mulier, claim 23 also cannot be anticipated by Mulier. For example, the specified functions of the differential current density electrode means limitation are not provided by Mulier. The specified function is "producing a first current density at the first electrode surface and a second current density at the second electrode surface, when a current is delivered via the conductor, wherein the first current density is smaller than the second current density so that the second electrode surface forms a high impedance and low polarization stimulating electrode." The function specifies that the second current density at the second electrode surface is greater than the first current density. Also, the second current density is at the second electrode surface, which is the surface that is affixed to the myocardial tissue to be stimulated.

The Examiner contends that Mulier produces differential current densities at the helical electrode 502 and the ring electrode 520. The contention is that the delivery of Ringer's solution, which is dispensed from the hollow helical electrode 502 and allegedly produces a "wider affected area," which in turn allegedly produces a *reduced current density* than exists at ring electrode 520. However, since helical electrode 502 is affixed to the tissue, helical electrode 502 would have to be the "second electrode surface" and the ring electrode 520 would have to be the "first electrode surface." But, according to the Examiner, the current density at helical electrode 502 is less than the current density at the ring electrode 520. Accordingly, by the Examiner's own admission, Mulier does not perform a differential current density function relative to first and second electrode surfaces as specified in the function of the differential current density electrode means of claim 23.

Applicant submits that Mulier does not perform the specified functions of the differential current density electrode means and does not anticipate claim 23.

Furthermore, claims 24, 25, 27- 29, 30, and 31-35 are not obvious from a combination of references that includes Mulier applied as in the anticipation rejection of claim 23.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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